IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC.,

Plaintiff,

v.

DAIICHI SANKYO CO., LTD.,

Defendant,

ASTRAZENECA PHARMACEUTICALS LP,
AND ASTRAZENECA UK LTD.,

Intervenor-Defendants.

Case No. 2:20-cv-00337-JRG

DEFENDANTS' NOTICE PURSUANT TO 35 U.S.C. § 282

Pursuant to 35 U.S.C. § 282, Defendant Daiichi Sankyo Company, Limited ("Daiichi Sankyo Japan") and Intervenor-Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. ("AstraZeneca") (collectively, "Defendants"), hereby identify the following materials that may be relied upon to invalidate U.S. Patent No. 10,808,039 ("the '039 patent") and/or show the state of the art relative to the asserted patent.

Defendants have already provided notice to Plaintiff Seagen Inc. ("Seagen") of the identity of certain publications, patents, and persons within the ambit of 35 U.S.C. § 282, through the pleadings and correspondence in this case, including but not limited to, invalidity contentions; expert witness reports; deposition testimony provided by party and non-party witnesses; exhibits introduced at deposition taken by the parties; Defendants' response to interrogatories, request for admission, and requests for production; documents produced in the litigation; Defendants' disclosures under Rule 26; Defendants' motion for summary judgment of anticipation; the parties'

motions *in limine* and motions to strike briefing; the materials disclosed in Defendants' trial exhibit list; and/or the joint pre-trial order. Defendants expressly incorporate herein by reference all of the publications, patents, patent applications, and specifications of persons within the ambit of 35 U.S.C. § 282 previously cited in these pleadings, testimony, correspondence, and other materials. To the extent not listed above, Defendants also incorporate by reference all art listed on the face of the '039 patent or identified in the prosecution history of that patent.

Defendants may also rely on the patentees/authors of the patents and publications listed below. Pursuant to the statutory provisions of 35 U.S.C. § 282, Defendants further refer to the list of identified patents, publications, materials, and persons below. The inclusion of the references listed below in this notice should not be construed as a representation that Defendants will use every one of the references in its presentation of evidence at trial. Nor should it be understood or taken as implied that reliance upon all of these materials is necessary to Defendants' defenses. Additionally, Defendants reserve the right to amend and/or supplement this notice to add items to this statement that were inadvertently omitted.

A. Patents, Patent Applications, and File Histories

Exhibit No.	Patent / Application No.	Production No.
DX-0073	U.S. Patent Application Publication No. 2016/0303254	DSC_ENHERTU_00015719 DSC_ENHERTU_00015835
DX-0156	U.S. Patent No. 11,116,847	DSC_ENHERTU_00390746 DSC_ENHERTU_00390859
DX-0144	U.S. Patent No. 8,871,720	DSC_ENHERTU_00390259 DSC_ENHERTU_00390347
DX-0153	U.S. Patent Application Publication No. 2017/0247412	DSC_ENHERTU_00390478 DSC_ENHERTU_00390713
DX-0209	United States Patent No. 8,592,576	DSC_ENHERTU_00391536 DSC_ENHERTU_00391574
DX-0238	United States Patent No. 4,981,979	DSC_ENHERTU_00395244 DSC_ENHERTU_00395260

DX-0240	United States Patent No. 5,525,338	DSC_ENHERTU_00395271 DSC_ENHERTU_00395284
DX-0239	United States Patent No. 5,024,834	DSC_ENHERTU_00395261 DSC_ENHERTU_00395270
DX-0071	Excerpt from File History of U.S. Patent Application No. 12/016,978	DSC_ENHERTU_00015710 DSC_ENHERTU_00015714
DX-0208	Excerpt from File History of U.S. Patent Application No. 12/016,978	DSC_ENHERTU_00391528 DSC_ENHERTU_00391535

B. Publications

Exhibit No.	Publication	Production No.
DX-0109	Y. Ogitani et al., *DS-8201a, A Novel HER2-Targeting ADC with a Novel DNA Topoisomerase I Inhibitor, Demonstrates a Promising Antitumor Efficacy with Differentiation from T-DM1*, 22 CLIN. CANCER RES. 5097 (2016)	DSC_ENHERTU_00025303 DSC_ENHERTU_00025315
DX-0110	Y. Ogitani et al., *Bystander Killing Effect of DS-8201a, a Novel Anti-Human Epidermal Growth Factor Receptor 2 Antibody-Drug Conjugate, in Tumors with Human Epidermal Growth Factor Receptor 2 Heterogeneity*, 107 CANCER SCI. 1039 (2016)	DSC_ENHERTU_00025316 DSC_ENHERTU_00025326
DX-0111	Y. Abe et al., *Development of New ADC Technology with Topoisomerase I Inhibitor*, in Antibody Engineering & Therapeutics 2015 (San Diego, CA)	DSC_ENHERTU_00025327 DSC_ENHERTU_00025327
DX-0078	J. Lambert & C. Morris, *Antibody-Drug Conjugates (ADCs) for Personalized Treatment of Solid Tumors: A Review*, 34 ADV. THER. 1015 (2017),	DSC_ENHERTU_00015910 DSC_ENHERTU_00015930
DX-0077	A. Beck et al., *Strategies and Challenges for the Next Generation of Antibody-Drug Conjugates*, 16 NAT. REV. DRUG DISCOV. 315 (2017),	DSC_ENHERTU_00015887 DSC_ENHERTU_00015909
DX-0082	J. McCombs & S. Owen, *Antibody Drug Conjugates: Design and Selection of Linker, Payload and Conjugation Chemistry*, 17(2) AAPS J. 339 (2015),	DSC_ENHERTU_00016046 DSC_ENHERTU_00016058
DX-0166	J. Tong et al., *An Insight into FDA Approved Antibody-Drug Conjugates for Cancer Therapy*, 26 Molecules 5847 (2021)	DSC_ENHERTU_00390993 DSC_ENHERTU_00391015

Exhibit No.	Publication	Production No.
DX-0186	*ADC Drugs with New Targets Clinical Pipeline Review*, Biopharma PEG, https://www.biochempeg.com/article/202.html	DSC_ENHERTU_00391277 DSC_ENHERTU_00391284
DX-0064	T. Nakada et al., *The Latest Research and Development into the Antibody-Drug Conjugate, [fam-] Trastuzumab Deruxtecan (DS-8201a), for HER2 Cancer Therapy*, 67 Chem. Pharm. Bull. 173 (2019)	DSC_ENHERTU_00011871 DSC_ENHERTU_00011883
DX-0204	L. Gauzy-Lazo et al., Advances in Antibody-Drug Conjugate Design: Current Clinical Landscape and Future Innovations, 25 SLAS Discovery 843 (2020)	DSC_ENHERTU_00391475 DSC_ENHERTU_00391500
DX-0084	B. Nolting, *Linker Technologies for Antibody-Drug Conjugates*, 1045 Antibody-Drug Conjugates 71 (2013)	DSC_ENHERTU_00016088 DSC_ENHERTU_00016117
DX-0083	D. Leung et al., *Antibody Conjugates-Recent Advances and Future Innovations*, 9 Antibodies 2 (2020)	DSC_ENHERTU_00016061 DSC_ENHERTU_00016087
DX-0088	J. Lambert, *Design Factors Important for Antibody-Drug Conjugate (ADC) Payloads*, 71 Drug Discoveries 31 (2019)	DSC_ENHERTU_00016180 DSC_ENHERTU_00016205
DX-0072	R. Kolakowski et al., *The Methylene Alkoxy Carbamate Self-Immolative Unit: Utilization for the Targeted Delivery of Alcohol-Containing Payloads with Antibody-Drug Conjugates*, 55 Angew. Chem. Int. Ed. 7948 (2016)	DSC_ENHERTU_00015715 DSC_ENHERTU_00015718
DX-0087	J. Lambert, *Drug-Conjugated Monoclonal Antibodies for the Treatment of Cancer*, 5 Current Opinion Pharmacology 543 (2005)	DSC_ENHERTU_00016173 DSC_ENHERTU_00016179
DX-0093	M. Dorywalska et al., *Molecular Basis of Valine-Citrulline-PABC Linker Instability in Site-Specific ADCs and Its Mitigation by Linker Design*, 15 Molecular Cancer Therapeutics 958 (2016)	DSC_ENHERTU_00016237 DSC_ENHERTU_00016250
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DX-0104	N. Caculitan et al., *Cathepsin B is Dispensable for Cellular Processing of Cathepsin B-Cleavable Antibody-Drug Conjugates*, 77 Cancer Research 7027 (2017)	DSC_ENHERTU_00016368 DSC_ENHERTU_00016379
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DX-0089	H. Tang et al., *The Analysis of Key Factors Related to ADCs Structural Design*, 10(373) Frontiers Pharmacology Art. (2019)	DSC_ENHERTU_00016206 DSC_ENHERTU_00016216
DX-0085	W. Widdison et al., *Factors Involved in the Design of Cytotoxic Payloads for Antibody-Drug Conjugates*, Antibody-Drug Conjugates and Immunotoxins 93 (2013)	DSC_ENHERTU_00016118 DSC_ENHERTU_00016140
DX-0160	H. Donaghy, *Effects of Antibody, Drug and Linker on the Preclinical and Clinical Toxicities of Antibody-Drug Conjugates*, 8 mAbs 659 (2016)	DSC_ENHERTU_00390929 DSC_ENHERTU_00390942
DX-0096	S. Yan et al., *Molecular Regulation of Human Cathepsin B: Implication in Pathologies*, 384 Biol. Chem. 845 (2003)	DSC_ENHERTU_00016269 DSC_ENHERTU_00016278
DX-0098	S. Gao et al., *Cathepsin G and Its Role in Inflammation and Autoimmune Diseases*, 33 Arch. Rheumatol. 498 (2018)	DSC_ENHERTU_00016303 DSC_ENHERTU_00016309
DX-0099	J. Reiser et al., *Specialized Roles for Cysteine Cathepsins in Health and Disease*, 120 J. Clin. Invest. 3421 (2010)	DSC_ENHERTU_00016310 DSC_ENHERTU_00016321
DX-0100	H. Ruan et al., *Targeting Cathepsin B for Cancer Therapies*, 56 Horiz. Cancer Res. 23 (2015)	DSC_ENHERTU_00016322 DSC_ENHERTU_00016333
DX-0097	E. Vidak et al., *Cysteine Cathepsins and Their Extracellular Roles: Shaping the Microenvironment*, 8 Cells 264 (2019)	DSC_ENHERTU_00016279 DSC_ENHERTU_00016302
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DX-0102	S. Kumari et al., *New Insight on the Role of Plasminogen Receptor in Cancer Progression*, 8 Cancer Growth & Metastasis 35 (2015)	DSC_ENHERTU_00016347 DSC_ENHERTU_00016354
DX-0103	Y. Cantres-Rosario et al., *HIV Infection Induces Extracellular Cathepsin B Uptake and Damage to Neurons*, 9 Scientific Reports (2019)	DSC_ENHERTU_00016355 DSC_ENHERTU_00016367
DX-0196	Solid Tumor, NIH National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/solid-tumor	DSC_ENHERTU_00391404 DSC_ENHERTU_00391404
DX-0189	Definition of blood cancer, Cancer.gov, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/blood-cancer	DSC_ENHERTU_00391315 DSC_ENHERTU_00391315
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DX-0183	J. Masters et al., *Clinical Toxicity of Antibody Drug Conjugates: A Meta-Analysis of Payloads*, 36 Invest New Drugs 121 (2018)	DSC_ENHERTU_00391231 DSC_ENHERTU_00391245
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DX-0171	O. Trédan et al., *Drug Resistance and the Solid Tumor Microenvironment*, 99 J. Nat'l Cancer Inst. 1441 (2007)	DSC_ENHERTU_00391073 DSC_ENHERTU_00391086
DX-0188	K. Fenn et al., *Sacituzumab Govitecan: Antibody-Drug Conjugate in Triple Negative Breast Cancer and Other Solid Tumors*, 55 Drugs Today 575 (2019)	DSC_ENHERTU_00391301 DSC_ENHERTU_00391314
DX-0148	S. Kaur et al., *Bioanalytical Assay Strategies for the Development of Antibody-Drug Conjugate Biotherapeutics*, 5 Bioanalysis 201 (2013)	DSC_ENHERTU_00390405 DSC_ENHERTU_00390430
DX-0203	O. Saad et al., *Bioanalytical Approaches for Characterizing Catabolism of Antibody-Drug Conjugates*, 7(13) Bioanalysis 1583 (2015)	DSC_ENHERTU_00391453 DSC_ENHERTU_00391474
DX-0150	D. Su et al., L*inker Design Impacts Antibody-Drug Conjugate Pharmacokinetics and Efficacy via Modulating the Stability and Payload Release Efficiency*, 12 Frontiers in Pharmacology (2021)	DSC_ENHERTU_00390441 DSC_ENHERTU_00390448
DX-0213	G. Dubowchik et al., *Cathepsin B-Sensitive Dipeptide Prodrugs. 2. Models of Anticancer Drugs Paclitaxel (Taxol®), Mitomycin C and Doxorubicin*, 8 Bioorganic Medicinal Chemistry Letters 3347 (1998)	DSC_ENHERTU_00391625 DSC_ENHERTU_00391630
DX-0215	G. Dubowchik et al., C*athepsin B-Sensitive Dipeptide Prodrugs. 1. A Model Study of Structural Requirements for Efficient Release of Doxorubicin*, 8 Bioorganic Medicinal Chemistry Letters 3341 (1998)	DSC_ENHERTU_00391635 DSC_ENHERTU_00391640
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DX-0140	S. Jordans et al., *Monitoring Compartment-Specific Substrate Cleavage by Cathepsins B, K, L, and S at Physiological pH and Redox Conditions*, 10 BMC Biochemistry 23 (2009)	DSC_ENHERTU_00390223 DSC_ENHERTU_00390237
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DX-0185	M. Barok et al., *Trastuzumab Emtansine: Mechanisms of Action and Drug Resistance*, 16 Breast Cancer Research 209 (2014)	DSC_ENHERTU_00391253 DSC_ENHERTU_00391264
DX-0155	Y. Tai et al., *Novel Anti-B-Cell Maturation Antigen Antibody-Drug Conjugate (GSK2857916) Selectively Induces Killing of Multiple Myeloma*, 123 Blood 3128 (2014)	DSC_ENHERTU_00390735 DSC_ENHERTU_00390745
DX-0074	R. Singh et al., *A New Triglycyl Peptide Linker for Antibody-Drug Conjugates (ADCs) with Improved Targeted Killing of Cancer Cells*, 15 Mol. Cancer Ther. 1311 (2016)	DSC_ENHERTU_00015845 DSC_ENHERTU_00015855
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DX-0158	V. Kostova et al., *The Chemistry Behind ADCs*, 14 Pharmaceuticals 442 (2021)	DSC_ENHERTU_00390866 DSC_ENHERTU_00390911
DX-0070	J. Lambert et al., *Ado-trastuzumab Emtansine (T-DM1): An Antibody-Drug Conjugate (ADC) for HER2-Positive Breast Cancer*, 57 J. Med. Chem. 6949 (2014)	DSC_ENHERTU_00015694 DSC_ENHERTU_00015709
DX-0179	C. Liu et al., *Eradication of Large Colon Tumor Xenografts by Targeted Delivery of Maytansinoids*, 93 Proc. Natl. Acad. Sci. 8618 (1996)	DSC_ENHERTU_00391178 DSC_ENHERTU_00391183
DX-0205	R. Chari et al., *Immunoconjugates Containing Novel Maytansinoids: Promising Anticancer Drugs*, 52 Cancer Research 127 (1992)	DSC_ENHERTU_00391501 DSC_ENHERTU_00391507
DX-0079	V. Goldmacher et al., *Immunotoxins and Antibody-Drug Conjugates for Cancer Treatment*, Biomedical Aspects of Drug Targeting 291 (2002)	DSC_ENHERTU_00015931 DSC_ENHERTU_00015949
DX-0176	G. Phillips et al., *Targeting HER2-Positive Breast Cancer with Trastuzumab-DM1, an Antibody-Cytotoxic Drug Conjugate*, 68 Cancer Res. 9280 (2008)	DSC_ENHERTU_00391147 DSC_ENHERTU_00391158
DX-0202	J. Cassady et al., *Recent Developments in the Maytansinoid Antitumor Agents*, 52 Chem. Pharm. Bull. (2004)	DSC_ENHERTU_00391427 DSC_ENHERTU_00391452

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DX-0069	A. Tolcher, *Antibody Drug Conjugates: Lessons from 20 Years of Clinical Experience*, 27(12) Ann. Oncol. 2168 (2016)	DSC_ENHERTU_00015689 DSC_ENHERTU_00015693
DX-0182	J. Wright et al., *Summary of Results with Triethylene Thiophosphoramide*, 68 Annals. N.Y. Acad. Sci. 937 (1958)	DSC_ENHERTU_00391201 DSC_ENHERTU_00391230
DX-0174	G. Vassal et al., *Dose-Dependent Neurotoxicity of High-Dose Busulfan in Children: A Clinical and Pharmacological Study*, 50 Cancer Research 6203 (1990)	DSC_ENHERTU_00391122 DSC_ENHERTU_00391127
DX-0193	A. Reese et al., *Treatment of Retinoblastoma by Radiation and Triethylenemelamine*, 53 A.M.A. Archives of Ophthalmology 505 (1954)	DSC_ENHERTU_00391349 DSC_ENHERTU_00391361
DX-0187	A. Pardee et al., *Cancer Therapy with ß-Lapachone*, 2(3) Current Cancer Drug Targets 227 (2002)	DSC_ENHERTU_00391285 DSC_ENHERTU_00391300
DX-0192	National Cancer Institute, CHOP regimen, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/chop-regimen	DSC_ENHERTU_00391348 DSC_ENHERTU_00391348
DX-0198	FOLFOX, NIH National Cancer Institute, https://www.cancer.gov/about cancer/ treatment/drugs/folfox	DSC_ENHERTU_00391417 DSC_ENHERTU_00391417
DX-0138	C. Chitambar, *Gallium Nitrate Revisited*, 30(2) Seminars in Oncology (2003)	DSC_ENHERTU_00390207 DSC_ENHERTU_00390211
DX-0130	L. Hansen et al., *Altretamine*, 25 Annals of Pharmacotherapy 146 (1991)	DSC_ENHERTU_00390140 DSC_ENHERTU_00390146
DX-0178	M. Wall et al., *The Effects of Some Steroidal Alkylating Agents on Experimental Animal Mammary Tumor and Leukemia Systems*, J. Med. Chem., 12:810 (1969)	DSC_ENHERTU_00391169 DSC_ENHERTU_00391177
DX-0201	*Paclitaxel Albumin-stabilized Nanoparticle Formulation*, National Cancer Institute, https://www.cancer.gov/about-cancer/treatment/drugs/nanoparticlepaclitaxel	DSC_ENHERTU_00391425 DSC_ENHERTU_00391426
DX-0142	M. Studer et al., *Influence of a Peptide Linker on Biodistribution and Metabolism of Antibody-Conjugated Benzyl-EDTA. Comparison of Enzymatic Digestion in Vitro and in Vivo*, 3 Bioconjugate Chem. 424 (1992)	DSC_ENHERTU_00390244 DSC_ENHERTU_00390249
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Exhibit No.	Publication	Production No.
DX-0214	G. Dubowchik et al., *Doxorubicin Immunoconjugates Containing Bivalent, Lysosomally-Cleavable Dipeptide Linkages*, 12 Bioorganic Medicinal Chemistry Letters 1529 (2002)	DSC_ENHERTU_00391631 DSC_ENHERTU_00391634
DX-0090	M. Akaiwa et al., *Antibody-Drug Conjugate Payloads; Study of Auristatin Derivatives*, 68(3) Chem. Pharm. Bull. 201 (2020)	DSC_ENHERTU_00016217 DSC_ENHERTU_00016227
DX-0068	N. Joubert et al., *Antibody-Drug Conjugates: The Last Decade*, 13(9) Pharmaceuticals 245 (2020)	DSC_ENHERTU_00015637 DSC_ENHERTU_00015667
DX-0091	K. Norsworthy et al., *FDA Approval Summary: Mylotarg for Treatment of Patients with Relapsed or Refractory CD33-Positive Acute Myeloid Leukemia*, 23 Oncologist 1103 (2018)	DSC_ENHERTU_00016228 DSC_ENHERTU_00016233
DX-0092	R. Chari, *Expanding the Reach of Antibody-Drug Conjugates*, 7 ACS Medicinal Chemistry Letters 974 (2016)	DSC_ENHERTU_00016234 DSC_ENHERTU_00016236
DX-0199	P. Carl et al., *Communications to the Editor: A Novel Connector Linkage Applicable in Prodrug Design*, 24 J. Med. Chem. 479 (1981)	DSC_ENHERTU_00391418 DSC_ENHERTU_00391419
DX-0157	B. Teicher et al., *Nitrobenzyl Halides and Carbamates as Prototype Bioreductive Alkylating Agents*, 23 J. Med. Chem. 955 (1980)	DSC_ENHERTU_00390860 DSC_ENHERTU_00390865
DX-0163	B. Toki et al., P*rotease-Mediated Fragmentation of p-Amidobenzyl Ethers: A New Strategy for the Activation of Anticancer Prodrugs*, 67 J. Organic Chem. 1866 (2002)	DSC_ENHERTU_00390962 DSC_ENHERTU_00390970
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DX-0139	D. Storm et al., *Effect of Small Changes in Orientation on Reaction Rate*, 94 J. Amer. Chem. Soc. 5815 (1972)	DSC_ENHERTU_00390212 DSC_ENHERTU_00390222
DX-0170	K. Amsberry et al., *The Lactonization of 2'-Hydroxyhydrocinnamic Acid Amides: A Potential Prodrug for Amines*, 55 J. Org. Chem. 5867 (1990)	DSC_ENHERTU_00391062 DSC_ENHERTU_00391072
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All patentees, applicants, and authors of the patents and publications listed above.

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(with permission by Jennifer P. Ainsworth)

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was filed electronically in compliance with L.R. CV-5 on March 4, 2022. As of this date, all counsel of record had consented to electronic service and are being served with a copy of this document through the Court's CM/ECF system under L.R. CV-5(a)(3)(A).

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